

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: NYKJAER2

In re Application of:	)	Conf. No.: 5401
Anders NYKJAER	)	
	)	Art Unit:
	)	
Appln. No.: 10/550,488	)	Examiner:
	)	
Filed: March 25, 2004	)	Washington, D.C.
	)	
For: USE OF COMPOUNDS FOR THE	)	August 21, 2006
PREVENTION OF DRUG-INDUCED CELL	)	
TOXICITY	)	

**INFORMATION DISCLOSURE STATEMENT [IDS]**

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Randolph Building, Mail Stop Amendments  
401 Dulany Street  
Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[X] B. before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114; or



☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below):

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein either was

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this IDS.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant states as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein either was

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or



☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this IDS.

Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

☒ 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:

☐ A. Document(s) \_\_\_\_\_ is/are deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 37 CFR §1.98(c), a copy of each of the former document(s) is not enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

*(insert serial numbers and filing dates of prior applications)*

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made of record in accordance with 37 CFR §1.98(d). Per 37 CFR



§1.98(d), copies of these documents need not be filed in this application.

[X] 3. Documents AJ,AL is not in the English language. In accordance with 37 CFR §1.98(a)(3), Applicant states:

[X] An English translation of each document AL (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.

[ ] For documents \_\_\_\_\_, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.

[X] A concise explanation of the relevance of documents AJ,AL is found in the previously filed International search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.

[ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on the attached sheet.

[X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

[ ] 5. Other information being provided for the examiner's consideration follows:

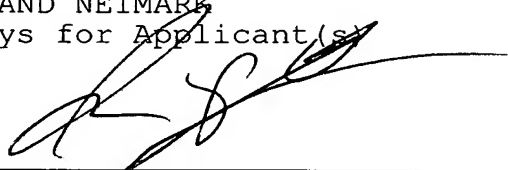


6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK  
Attorneys for Applicant(s)

By:

  
Iver P. Cooper  
Registration No. 28,005

IPC:dac  
624 Ninth Street, N.W., Suite 300  
Washington, D.C. 20001-5303  
Telephone: (202) 628-5197  
Facsimile: (202) 737-3528

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of 3

**Complete if Known**

Application Number	10/550,488
Filing Date	March 25, 2004
First Named Inventor	Anders NYKJAER
Group Art Unit	
Examiner Name	
Attorney Docket Number	NYKJAER2

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-5,773,444	06-30-1998	Ahn et al.	
	AB	US-5,409,915	04-25-1995	Farrell et al.	
	AC	US-6,177,434	01-23-2001	Kopke et al.	
	AD	US-6,130,217	10-10-2000	Arnold et al.	
		US-			
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	AE	GB 1,364,521	08-21-1974	Merck & Co. Inc.		
	AF	WO 03/080103 A1	10-02-2003	Max-Delbrück-Centrum		
	AG	WO 02/053519 A2	07-11-2002	Oridigm Corporation		
	AH	WO 99/02145	01-21-1999	Cambridge Neuro		
	AI	EP 0 483 634 A2	05-06-1992	Hoechst-Roussel		
	AJ	DE 100 53 506 A1	05-02-2002	Max-Delbrück-Centrum		
	AK	WO 89/05637	06-29-1989	U.S. Bioscience		
	AL	WO 01/12607 A2	02-22-2001	Lafon Labor		
	AM	WO 03/066572 A1	08-14-2003	Wisconsin Alumni Research		

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



Substitute for form 1449A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/550,488
		Filing Date	March 25, 2004
		First Named Inventor	Anders NYKJAER
		Group Art Unit	
		Examiner Name	
Sheet 2	of 3	Attorney Docket Number	NYKJAER2

NON PATENT LITERATURE DOCUMENTS / OTHER INFORMATION			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AN	JONES, M.M. et al., "Control of the Nephrotoxicity of Cisplatin by Clinically Used Sulfur-Containing Compounds"; Fundamental and Applied Toxicology, Vol. 18, pp.181-188, 1992	
	AO	MOESTRUP, S.K. et al., "Evidence that Epithelial Glycoprotein 330/Megalin Mediates Uptake of Polybasic Drugs"; J. Clin. Invest, Vol 96, pp.1404-1413, 1995	
	AP	BEGG, E.J. et al; "Aminoglycosides-50 years on"; Br J. Clin Pharmacy, Vol. 39, pp. 597-603, 1995	
	AQ	ERNFORS, P et al., "Protection of auditory neurons from aminoglycoside toxicity by neurotrophin-3"; Nature Medicine, Vol. 2, Number 4, pp463-467, April 1996	
	AR	LEE, S.M. et al., "Nitrendipine Protects Against Aminoglycoside Nephrotoxicity in the Rat"; Journal of Cardiovascular Pharmacology; 9 Suppl., S65-S69, 1987	
	AS	XUAN, W. et al., "Effects of Compound Injection of Pyrola Rotundifolia L and Astragalus Membranaceus BGE On Experimental Guinea Pigs" Gentamicin Ototoxicity"; Ann Otol Rhinol Laryngol, pp. 374-380, 1995	
	AT	SCHACHT, J. "Aminoglycoside ototoxicity: Prevention in sight?; Head and Neck Surgery, pp.674-677, 1998	
	AU	MILAM, K.M. et al., "Reduction in cis- Diamminedichloroplatinum (II)- induced Cytotoxicity, Sister Chromatid Exchange, and DNA Interstrand Cross-Links in 9L Cells Treated with the Polyamine Biosynthesis Inhibitor (2R, 5R)-6-Heptyne-2,5-diamine	
	AV	HEYS, S.D. et al., "Potentiation of the response to chemotherapy in patients with breast cancer by dietary Supplementation with L-arginine: results of a randomized controlled trial"; International Journal of Oncology; XP008033963, Vol. 12, pp.221-225, 1998	
	AW	TOMIDA, A. et al., Novel Mechanism of N-Solanesyl-N, N'-bis (3, 4-dimethoxybenzyl) ethylenediamine in Potentiation of Antitumor Drug Action on Multidrug-resistant and Sensitive Chinese Hamster Cells; Jpn. J. Cancer Res. Vol. 82, pp.127-133, January 1991	
	AX	FAN, D. et al., "Reversal of multidrug resistance in murine fibrosarcoma cells by thioxanthene flupentixol"; Investigational New Drugs, XP008033946, Vol. 12, pp.185-195, 1994	
	AY	Lin P. et al., "The Synthesis and In Vitro Cytotoxic Studies of Novel Bis-naphthalimidopropyl Polyamine Derivatives"; Bioorganic and Medicinal Chemistry Letters 10, pp. 1609-1612, 2000	

Examiner Signature	Date Considered
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3

of 3

**Complete if Known**

Application Number	10/550,488
Filing Date	March 25, 2004
First Named Inventor	Anders NYKJAER
Group Art Unit	
Examiner Name	
Attorney Docket Number	NYKJAER2

**NON PATENT LITERATURE DOCUMENTS / OTHER INFORMATION**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AZ	EDWARDS, M.L. et al., "Polyamine Analogues with Antitumor Activity"; J. Med. Chem; XP000604648, Vol. 33, pp. 1369-1375, 1990	
	BA	WIEBKIN, P. et al., "Inhibition of Metabolism-Mediated Cytotoxicity By 1, 1-Disubstituted Hydrazines in Mouse Mastocytoma (Line P815) Cells; Biochemical Pharmacology, XP-001199476, Vol. 31, No. 18, pp.2921-2928, 1982	
	BB	KONDRATOV, R.V. et al., "Small molecules that dramatically alter multidrug resistance phenotype by Modulating the substrate specificity of P-glycoprotein; PNAS, XP-002259950, Vol. 98, No. 24, November 20, 2001	
	BC	SCHMITZ, C. et al., "Megalin Deficiency Offers Protection from Renal Aminoglycoside Accumulation"; The Journal of Biological Chemistry; Vol. 277, No. 1, pp. 618-622, January 4, 2002	

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SignatureDate  
Considered

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